510(k) Summary

K023351

Submitted by:	Tracy Palmer Berns EXPERTech Associates, Inc. 100 Main Street, Suite 120 Concord, MA 01742 Telephone: 978-371-0066 Fax: 978-371-1676 E-mail: tberns@fdahelp.com
Date of summary	October 3, 2002
Device Trade Name	Magic® Infusion Catheter
Common Name	Continuous Flush Catheter
Classification Name	Catheter, Continuous Flush (21 CFR § 870.1210)
Predicate Device	Magic Infusion Catheter (K923368) submitted by Target Therapeutics, Inc. The subject device is the same device as the predicate, made by the same manufacturer.
Description	The subject device is intended to operate for regional infusion of contrast materials into selected vessels in the neurovasculature. Magic Infusion Catheters are intended to facilitate access through distant, tortuous vasculature. Progressive suppleness ranging from a highly flexible tip to a semi-rigid proximal section allows the catheter to be advanced by the physician. It is not intended for use in the coronary vasculature. Magic catheters are available in 1.8 and 1.5Fr and 165 and 155 cm in length and are available with an "olive" tip configuration.
Intended Use	Magic Infusion Catheters are intended for controlled, regional infusion into selected vessels.
Technological Characteristics	The subject device has the same technological characteristics as the predicate device. The only changes involve a change to the materials of the proximal shaft of the catheter and the tip marker, and a change in the catheter's coating. The proximal shaft in the subject Magic catheters is Polyamid, the tip marker is platinum, and the coating is a hydrophilic coating, Hydrospeed™. These changes do not affect the safety and effectiveness of the device.
Testing	Testing on the Magic catheter including biocompatibility, joint strength, shaft tensile strength, tip tensile strength, tip flexibility, static rupture strength, dynamic rupture strength, and flow rate tests were submitted in K923368 and demonstrated the substantial

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equivalence relative to the safety and effectiveness of the device. No changes have been made to the design or intended use of the product since the clearance of K923368. Testing demonstrated that the Magic catheter with the hydrophilic coating was non cytotoxic, non hemolytic, non pyrogenic, non mutagenic, non sensitizing and non irritating attesting to the catheter with the new coating's biocompatibility. Change of the material in the catheter's tip marker is not a significant change as the properties of the new material (platinum) is well understood. Testing on the catheter including the Polyamid section of the shaft demonstrated that the catheter was non cytotoxic, non hemolytic, non pyrogenic, non allergenic, non toxic, and non irritating.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Advanced Interventional Technologies
c/o Ms. Tracy Palmer Berns
Senior Consultant
Expertech Associates, Inc.
100 Main Street, Suite 120
Concord, Massachusetts 01742

Re: K023351
Trade Name: Magic® Infusion Catheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous flush catheter
Regulatory Class: II
Product Code: KRA
Dated: December 18, 2002
Received: December 19, 2002

Dear Ms. Berns:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K023351

Device Name: Magic® Infusion Catheter

Indications For Use:

The Magic Infusion Catheter is intended for regional infusion of contrast materials into selected vessels in the neurovasculature. The Magic Infusion Catheter may be used for controlled, regional infusion into selected vessels and is not intended for use in the coronary vasculature.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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Prescription Use X **OR** **Over-The-Counter Use**
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**